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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/215,257	12/18/1998	ANDREW Z. FIRE	PM256628	7602

7590 01/25/2002

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EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/215,257	Applicant(s) FIRE ET AL.	
	Examiner Karen A. Lacourciere	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see continuation sheet.*.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see continuation sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-23,25-35 and 39-46*.

   Claim(s) withdrawn from consideration: *7 and 24*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *19*.

10. ☒ Other: Interview Summary for Dec 3, 2001 attached. KAL 01-18-02

ANDREW WANG
PRIMARY EXAMINER

Continuation of 2. The amendment filed 01-08-2002 includes new claims which include new limitations, including, for example, introduction in the interstitial space. Further, newly submitted claims 47-51 would require consideration of the clarity of the language, for example, claim 50 introduces an issue under 112, as to how is an RNA introduced to an organism by feeding an unrelated second organism and what is being fed to that second organism. Claims 47-51 would require new consideration under enablement. The amendment to claim 39 would require a new search, as the scope of the claimed composition has been narrowed to exclude the prior art cited in the prior Office action (mailed 10-19-01). Applicant's amendments which remove the limitation wherein the region of complementarity is at least 25 nucleotides would not introduce an issue under 112, second paragraph (as discussed with Applicant in the informal interview on Dec 3, 2001), however, this amendment does introduce new issues with regard to art and would require a new search.

Continuation of 3. Applicant's reply has overcome the following rejection(s): All rejections of claims 12-14, 17-20, 23-25, 40-46, as all are canceled. The rejections of record for claims 1-6, 8-11, 15, 16, 21, 22, 26-35.

Continuation of 5. Applicant argues the enablement of the claims over the full scope claimed by citing specific examples in the art which do not address the full scope. For example, Applicant provides a methods of delivering nucleic acids by direct injection for muscle cells and delivery of nucleic acids orally, however, these methods provide delivery for a very limited scope, not the full scope claimed. Further, the rejection of record under 112, first prargraph (scope of enablement) is not based purely on delivery, but also on the unpredictable nature of RNAi in vertebrate organisms, as demonstrated in the art at the time of the invention. Individual examples of successful applications of RNAi in post-filing references do not support that the methods claimed could have been predictably practiced by one of ordinary skill in the art based upon the guidance in the specification at the time of the instant invention. The post-filing references indicate that certain structural features are required for the successful application of RNAi in mammals, such features were not appreciated by the instant application, nor by the art at the time of the invention, and therefore, do not enable the invention at the time of the invention. Further, the advertisement submitted from AGY therapeutics seems to support that at the time of the invention RNAi in mammals had enablement issues at the time of the invention, for example, stating "its application in mammalian cells until recently has had limited efficacy and possible unspecific inhibition".